

**LIBELED:** On or about 7-11-61, S. Dist. Ind.

**CHARGE:** 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for relief of flu, colds, chills, rheumatism, grippe, and associated conditions; and 502(f) (2)—the labeling of the article failed to bear the warning statement "Keep out of reach of children."

**DISPOSITION:** 10-20-61. Default—destruction.

**6870. Cobasal tablets and Cobaden injection.** (F.D.C. No. 46588. S. Nos. 97-902 R, 97-904 R.

**QUANTITY:** 21 cases, 12 100-tablet btls. each, and 10 1,000-tablet btls. of *Cobasal*; and 48 vials of *Cobaden injection*, at Rensselaer, N.Y., in possession of Rand Pharmaceutical Co., Inc.

**SHIPPED:** (*Cobasal tablets*) 2-1-61, from Worcester, Mass.; (*Cobaden injection*) 4-24-61, from Decatur, Ill.

**LABEL IN PART:** (Btl.) "Cobasal \* \* \* Each 2 Tablets contains: Dipyrone 0.125 Gm Para-amino-benzoic Acid 8 gr. Salicylamide 6 gr. Vitamin B-12 Activity 5 mcg. Distributed by Rand Pharmaceutical Company, Inc., Rensselaer, N.Y. Caution: \* \* \* Dosage: 2 tablets." and (vial and ctn.) "10 cc. No. 125 Multiple Dose Sterile Vial Cobaden \* \* \* Caution \* \* \* Manufactured for Rand Pharmaceutical Co., Inc., Rensselaer, N.Y. Each 1 cc. contains: Adenosine-5-Monophosphoric Acid 25 mg. (present as Sodium Salt) Vitamin B-12 (Crystalline) 60 mcg. \* \* \* Intramuscular."

**ACCOMPANYING LABELING:** Leaflets entitled "Cobaden Adenosine-5-monophosphoric acid plus Vitamin B<sub>12</sub>," "Adenosine with Vitamin B<sub>12</sub>" and "Cobasal (Rand) A new Anti-Rheumatic \* \* \* Alone or in conjunction with \* \* \* Cobaden."

**LIBELED:** 10-27-61, N. Dist. N.Y.

**CHARGE:** 502(a)—while held for sale, (*Cobasal tablets*) the labeling contained false and misleading representations that the article was adequate and effective for the treatment of neuritis; pruritus; pruritus due to penicillin sensitivity; chronic venous insufficiency; renal and gall-bladder colics; pneumonia; meningeal inflammations; cholelithiasis; iritis; and herpes; and to promote growth and body development; and the labeling also contained false and misleading representations that there were no contraindications for use of the article; and (*Cobaden injection*) the labeling contained false and misleading representations that the article was adequate and effective for the treatment of bursitis; osteoarthritis; pruritus ani, vulvae, and scroti; pruritus associated with penicillin reaction; and chronic venous insufficiency; and 502(f) (1)—(*Cobasal tablets*) the labeling failed to bear adequate directions for use, since its labeling failed to bear adequate information for use of the drug, including relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug, could use it safely and for the purposes for which it was intended.

**DISPOSITION:** 1-4-62. Default—destruction.

**6871. Devine's remedies.** (F.D.C. No. 46474. S. Nos. 6-282/5 T.)

**QUANTITY:** 144 10-oz. pkgs. of *10/2 Corn and Callous Reducer*; 864 5- or 3- or 1-fluid oz. tubes of *Kool-Foot Powder*; 576 3¼-oz boxes of *Per-Fo Foot-bath*; and 720 envelopes of *Karbo-Silekon Corn Reducer*, at Boston, Mass., in possession of Darryl Jensen.

**SHIPPED:** 8-9-61, from Chicago, Ill., by Devine's Remedies, Inc.

**LABEL IN PART:** (Pkg.) "Devine's New 10/2 Free 'Karbo-Silekon' Eraser Enclosed"; (tube) "Devine's Kool-Foot"; (box) "Improved Devine's Per-Fo \* \* \* Devine's Per-Fo a foot and body bath"; and (envelope) "Devine's Karbo-Silekon Corn & Callus Reducer."

**ACCOMPANYING LABELING:** Promotional material reading in part "Feet Hurt Burn Tired Itch Ache? Then Use Devine's Kool Foot \* \* \* Pain Sufferers \* \* \* Use Devine's Zina-Ray Oil."

**LIBELED:** 9-29-61, Dist. Mass.

**CHARGE:** 502(a)—when shipped, the labeling contained false and misleading representations that the article was adequate and effective (*10/2 Corn and Callous Reducer*) for the prevention of athlete's foot, reducing corns, and preventing corns and calluses; (*Kool-Foot Powder*) for overcoming athlete's foot, relieving sunburn, bruises, external cuts, and stiffness and soreness of joints; and (*Karbo-Silekon Corn Reducer*) for reducing corns and calluses; and 502(f) (1)—the labeling failed to bear adequate directions for use for the purposes for which the articles were intended, namely, as a treatment for (*10/2 Corn and Callous Reducer*) relieving in four days time, corns, calluses, fungus of the feet and athlete's foot; (*Kool-Foot Powder*) relieving in one minute, inflamed or aching feet, any kind of rash, sunburn, bunions, and athlete's foot; (*Per-Fo Footbath*) cleansing and purifying the inside of the feet, making one feel that they have "new feet," flushing out all the impurities in the feet; and (*Karbo-Silekon Corn Reducer*) removing corns completely, which were the conditions and purposes for which the articles were offered, in oral statements made by Darryl Jensen, salesman for Devine's Remedies, Inc.

**DISPOSITION:** 11-27-61. Default—destruction.

**6872. Kneipp herb teas.** (F.D.C. No. 46578. S. Nos. 39-708/20 T, 39-828/32 T, 39-834/40 T, 41-801/2 T.)

**QUANTITY:** 98 cases of 165 dozen pkgs., 6 cases of 377 cans, and 9 cases of 327 cans at New York, N.Y., in possession of Alfred L. Ettlinger, Inc.

**SHIPPED:** On various dates between 1960 and 1961, from Wurzburg, Germany.

**LABEL IN PART:** (Pkg.) "Kneipp Carminative Herb Tea Contents: ca. 3 oz."; (cans) "Kneipp Carminative Instant Tea \* \* \* Contents: ca. 120 g."

**ACCOMPANYING LABELING:** Leaflet entitled "Imported Kneipp Herb Teas Kneipp Pressan (Instant) Teas."

**RESULTS OF INVESTIGATION:** Each package and each can bore a number corresponding to a number in the leaflet which indicated on the leaflet the condition for which the tea was to be used. The dealer had copies of the leaflet printed locally.

**LIBELED:** 10-17-61, S. Dist. N.Y.

**CHARGE:** 502(a)—while held for sale, the labeling of some of the articles contained false and misleading representations that the articles were adequate and effective for the treatment of diseases of the nerves, diseases of the kidneys and bladder, rheumatism, insomnia, for reducing body weight, to promote the health of the family, colds and flu, diseases of the gallbladder and liver, to purify the blood, diseases of the arteries, asthma, to promote the appetite, hemorrhoids, to control the uric acid in the body, diseases of the heart and circulatory system, cough, to control silicic acid in the body, and diseases of the stomach; and the label statement of some of the articles "Carminative